K080235

April 24, 2008

510(k) SUMMARY

CONTACT

Douglas L. Harris
Greiner Bio-One North America, Inc.
4238 Capital Drive
Monroe, NC 28110

APR 24 2008

NAME OF DEVICE

Trade Name:	VACUETTE® Safety Infusion Set
Regulation Number:	880.5440
Classification Name:	IV Fluid Transfer Set

PREDICATE DEVICE

Intended Use: Nipro® SafeTouch Safety Scalp Vein Set (K011297)

Description: Greiner VACUETTE® Safety Blood Collection Set (K011786)

DEVICE DESCRIPTION

INTENDED USE: The VACUETTE® Safety Infusion Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a luer connector. The VACUETTE® Safety Infusion Set is used for blood collection and/or the short-term infusion of intravenous fluids. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

PRODUCT DESCRIPTION: The safety feature is easily operated through the release of a latch mechanism whereby the user slides a winged cover over the needle, as it is removed from the patient. Once the needle is covered, the safety cover locks in place. This mechanism is identical to that of the Greiner VACUETTE® Safety Blood Collection Set (K011786).

The VACUETTE® Safety Infusion Set will be available in 2 configurations of needle gauge (21G and 23G) and one tubing length (7.5 inches).

The devices are packaged as sterile and are labeled for single use only. There is no ability to clean and reuse these devices. The devices were tested for sterility, pyrogenicity and systemic injection testing and were found to be biocompatible.

SUBSTANTIAL EQUIVALENCE

The VACUETTE® Safety Infusion Set is substantially equivalent to the Nipro® SafeTouch Safety Scalp Vein Set in intended use. Since the VACUETTE® Safety Infusion Set represents a new intended use for the VACUETTE® Safety Blood Collection Set, its design, safety feature, raw materials, biocompatibility, and performance are identical to the previously FDA-cleared Greiner VACUETTE® Safety Blood Collection Set. In addition, both devices are manufactured in the same plant – Nipro (Thailand) Corp. Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Greiner Bio-One North America, Incorporated
C/O Ms. Judith Smith
Director-IVD/Medical Devices
Beaufort Advisors, L.L.C.
13801 Eck Road
Hydes, Maryland 21082

APR 24 2008

Re: K080235
Trade/Device Name: VACUETTE® Safety Infusion Set
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: January 29, 2008
Received: January 30, 2008

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080235

Device Name: **VACUETTE®** Safety Infusion Set

Indications For Use:

The VACUETTE® Safety Infusion Set is a single-use, sterile, winged blood collection needle bonded to a flexible tubing with a luer connector. The VACUETTE® Safety Infusion Set is used for blood collection and/or the short-term infusion of intravenous fluids. The winged needle is designed with a safety shield, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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